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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/434,254	11/05/1999	JAMES L. SAY	11554.6USII	3737
23552	7590	06/01/2004	EXAMINER	
MERCHANT & GOULD PC			MALLARI, PATRICIA C	
P.O. BOX 2903			ART UNIT	PAPER NUMBER
MINNEAPOLIS, MN 55402-0903			3736	

DATE MAILED: 06/01/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/434,254	SAY ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 March 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,4-17,19 and 21-25 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 19,21 and 22 is/are allowed.
- 6) Claim(s) 1-17,23 and 25 is/are rejected.
- 7) Claim(s) 24 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

This Office action is non-final. The indicated allowability of claim 18, which is now cancelled and the subject matter of which is incorporated into claim 1, is withdrawn in view of the references US Patent No. 4,671,288 to Gough and US Patent No. 5,503,728 to Kaneko et al. Rejections based on the newly cited references follow.

Drawings

This application has been filed with informal drawings, acceptable for examination purposes only. Upon allowance of the application, formal drawings will be required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 6, 7, and 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,671,288 to Gough in view of US Patent No. 5,503,728 to Kaneko et al. Gough teaches an electrochemical sensor comprising a plurality of electrically conductive electrodes 16, 18 a sensing material 20 coating at least some of the electrodes, and an electrically insulating layer 27 positioned about the plurality of electrodes 16, 18. The insulating layer 27 forms an analyte barrier that surrounds the conductive electrodes 16, 18, and that defines a plurality of openings 12,

14 for allowing an analyte to access the sensing material 20 (fig. 3; col. 2, lines 57-68; col. 3, lines 50-58 of Gough). Gough is silent as to the construction of the electrodes.

However, Kaneko discloses an electrochemical sensor comprising an electrode, wherein the electrode may consist of a bundle of carbon fibers (col. 3, line 48-col. 4, line 4; col. 6, lines 3-19; col. 7, lines 45-47 of Kaneko et al.) Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the carbon fiber electrode of Kaneko as the electrode of Gough, since Gough teaches using an electrode in an electrochemical sensor and Kaneko describes an appropriate electrode for an electrochemical sensor.

Regarding claims 7 and 9-14, the sensing material includes a redox compound, wherein oxidase enzymes are redox enzymes that catalyzes the oxidation of an analyte (col. 2, lines 66-68 of Gough). With further regard to claims 11 and 12, the analyte to be sensed may be lactate and the enzyme may be lactate oxidase (claims 4 and 5 of Gough). With further regard to claims 13 and 14, when glucose is the analyte to be sensed, the oxidase enzyme is glucose oxidase (col. 5, lines 39-45 of Gough).

Regarding claims 15-17, the fibers may form a sheet, may be interwoven, or may form a piece of fabric (col. 6, lines 15-19 of Kaneko).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Kaneko, as applied to claims 1, 4, 6, 7, and 9-17 above, and further in view of US Patent No. 5,515,848 to Corbett, III et al. Gough, as modified fails to teach the insulating layer as being polyurethane. However, Corbett, III describes polyurethane as an insulating coating for conductors in a biological sensor (col. 3, lines 12-16 of Corbett,

III). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use polyurethane as the insulating layer of Gough, as modified by Kaneko, since Gough as modified teaches a sensor comprising an insulating layer, and Corbett, III discloses polyurethane as an appropriate insulating layer in such a sensor.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Kaneko, as applied to claims 1, 4, 6, 7, and 9-17, above, and further in view of US Patent No. 5,262,035 to Gregg et al. Gough, as modified, fails to teach a transition metal complex with one or more organic ligands as the redox compound. However, Gregg discloses an enzyme electrode system based on a crosslinked redox polymer having a redox enzyme bound within itself, where the polymer may include a plurality of transition metal complexes, each complex having a plurality of organic ligands (col. 5, lines 3-6; claims 1 and 2 of Gregg et al.) Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the crosslinked redox polymer of Gregg et al. as the redox compound of Gough, as modified by Kaneko, in order to, among other things, stabilize the enzyme thus retarding thermal denaturation (col. 3, lines 20-25; col. 7, lines 20-50 of Gregg et al.).

Claims 23 and 25 are rejected under 35 U.S. C. 103(a) as being unpatentable over US Patent No. 4,945,896 to Gade in view of Gough, and further in view of Kaneko et al. Gade discloses a retractor device 10 having surgical retractor blade 18 and a sensor 20 positioned adjacent to the retractor blade 18 for sensing parameters of a tissue being compressed by the blade 18 (col. 3, line 54-col. 4, line 19 of Gade). Gade notes that the sensor may be any device that directly measures a parameter indicative

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of cellular metabolism or tissue oxygenation (col. 2., lines 44-49; col.7, lines 57-63 of Gade), but fails to specify a lactate sensor.

However, Gough teaches a lactate sensor comprising electrodes 16, 18, a sensing material 20 that includes a redox compound for oxidizing lactate (claims 4 and 5 of Gough) coating the electrodes, and an insulating layer 27 positioned about the electrodes and defining a plurality of openings 12, 14 for allowing access to the sensing material 20 (col. 2, lines 58-68; col. 3, lines 50-55; fig. 3 of Gough). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the sensor of Gough as the sensor of the retractor device of Gade, since Gade discloses using a sensor which directly measures a parameter indicative of cellular metabolism or tissue oxygenation and Gough describes such a sensor, where lactate is a parameter indicative of cellular metabolism and tissue oxygenation (see col. 19, lines 36-38 of US Patent No. 4,833,083 to Saxena; also see col. 27, lines 35-38 and col.34, line 39 of US Patent No. 5,814,601 to Winslow et al.)

The device of Gade in view of Gough is silent as to the composition of the electrodes 16, 18. However, Kaneko describes an electrochemical sensor comprising an electrode, wherein the electrode may consist of a bundle of carbon fibers (col. 3, line 48-col. 4, line 4; col. 6, lines 3-19; col. 7, lines 45-47of Kaneko). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the carbon fiber electrode of Kaneko as the electrode of Gade in view of Gough, since Gade, as modified uses an electrode in an electrochemical sensor and Kaneko describes an appropriate electrode for an electrochemical sensor.

Allowable Subject Matter

Claims 19-22 are allowed.

Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

With regard to claims 19-22 and 24, the prior art of record fails to teach or fairly suggest a retractor device comprising a lactate sensor positioned adjacent a retractor blade wherein the lactate sensor engages a surgical pad.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Mallari
Patricia Mallari
Patent Examiner
Art Unit 3736

Mary Beth Jones
MARY BETH JONES
ACTING SUPERVISORY PATENT EXAMINER